In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-453V

KEYONNA MICHIE, *Parent and Natural Guardian of K.W., a minor,*	*	Chief Special Master Corcoran
Petitioner,	*	Filed: December 4, 2023
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Robert Krakow, Law Office of Robert Krakow, P.C., New York, NY, for Petitioner.

Sarah C. Duncan, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

Keyonna Michie, on behalf of her child, K.W., filed a petition on March 27, 2019, seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] ECF No. 1. Petitioner alleged that the measles-mumps-rubella ("MMR") vaccine K.W. received on April 8, 2016, caused him to develop immune thrombocytopenic purpura ("ITP")—a Table claim (although she also alleged that other vaccines received at the same time were causal as well). Pet. at 1.

Respondent asserts that K.W. cannot satisfy the statutory prerequisite that petitioners demonstrate that their vaccine-related injury or the residual effects thereof lasted for more than six

[1] "Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id."*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10–37 (2012) (hereinafter "Vaccine Act" or "the Act"). Individual section references hereafter shall refer to § 300aa of the Act.

months. *See* Rule 4(c) Report, dated June 21, 2021 (ECF No. 64) at 6; Section 11(c)(1)(D)(i). On these grounds, Respondent moves to dismiss Petitioner's claim. *Id.* at 7.

In reaction, I ordered Petitioner to show cause why the claim should not be dismissed, and the parties have fully briefed the matter. Petitioner's Brief, dated May 8, 2023 (ECF No. 82) ("Br."); Respondent's Brief, dated July 10, 2023 (ECF No. 85) ("Opp."); Petitioner's Reply, dated August 10, 2023 (ECF No. 87) ("Reply"). For the reasons set forth below, I find that Petitioner has failed to satisfy the severity requirement, and therefore her claim warrants dismissal.

I. Factual Background

K.W. was born April 2, 2016—and was thus about a year old when he received the MMR and two other vaccines on April 8, 2016, at his pediatrician's office. Ex. 2 at 99–104. Ten days later, he was brought to Jacobi Medical Center in Bronx, New York, for treatment of an erythematous blanching macular rash that had appeared on his chest, back, and arms. Ex. 4 at 109, 111. He displayed no petechiae[3] at this time, however, was in no distress, and his temperature was minimally elevated to 100 degrees. *Id.* The exam was otherwise deemed normal and the rash nonspecific, and no laboratory evaluation was requested or performed. *Id.*

The following month, on May 12, 2016, K.W. was admitted to the hospital after an ER visit. Ex. 4 at 122–25. The history noted onset of a rash, described as small red spots on his face, over the prior two days, expanding to his chest, arms, and legs. *Id.* On exam he was asymptomatic, without fever or signs of infection, but an initial complete blood count ("CBC")[4] revealed platelet count of 7,000—a significantly low figure.[5] *Id.* at 150. K.W. thereafter underwent a hematology consultation resulting in a formal ITP diagnosis. *Id.* at 147. He was treated with IVIG, and his platelets increased to 47,000 the next day. *Id.* at 154.

K.W. was subsequently discharged, and Petitioner was advised to bring him back for subsequent outpatient treatment. Ex. 4 at 142, 146, 164–65. But he was readmitted that same month for further observation after vomiting (although this symptom was later attributed to a viral infection independent of his ITP). *Id.* at 187–92. By May 18, 2016, K.W.'s platelet count had

[3] A petechiae is "a pinpoint, nonraised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage." *Petechia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=38200 (last visited on Nov. 13, 2023).

[4] Platelet counts reveal "the number of platelets (thrombocytes) per cubic milliliter of blood." *Crabbe v. Sec'y of Health & Human Servs.*, No. 10-762V, 2011 WL 4436724, at *2 n.9 (citing Pagana et al., *Mosby's Manual of Diagnostic and Laboratory Tests* 416 (4th ed. 2010)).

[5] A normal platelet count falls within a range of 150,000 to 400,000 platelets per microliter. *Thrombocytopenia*, NIH National Heart Lung and Blood Institute, https://www.nhlbi.nih.gov/health/thrombocytopenia (last accessed December 1, 2023)

increased to 83,000. Ex. 21 at 17. It subsequently fluctuated somewhat (33,000 in early June, compared with 87,000 as reported at a mid-July 15-month well-child visit), but with no reports of additional petechiae/bruising. *Id.* at 16; Ex. 2 at 122–26. And by late July 2016 (now a bit more than three months post-vaccination), his count had risen to 199,000. Ex. 9 at 194; Ex. 21 at 15.

K.W. received additional treatment thereafter for typical pediatric concerns, but no further evidence of dangerously-low platelet counts has been filed in this case (even if Petitioner *represented* to non-hematology treaters that this was the case), and there is no evidence of further bruising either. *See, e.g.*, Ex. 2 at 147–52 (October 2016 pediatric care visit at which time Petitioner informed a treater that K.W.'s levels were then at 30,000—although no evidence has been filed in this case corroborating this contention—and treater note from the time observed no bruising).[6]

Subsequent hematologic treatment visits, by contrast, confirm normal platelet levels. *See, e.g.*, Ex. 19 at 214, Ex. 21 at 14 (December 2016 visit—platelet levels of 326,000, deemed within normal limits); Ex. 2 at 200, Ex. 7 at 4 (May 2017 visit—platelet levels of 379,000). In June 2017, bruising on K.W.'s legs was observed during a pediatric visit, but the treater deemed it unlikely to reflect ITP—since his platelet levels were measured to be within normal limits. Ex. 8 at 22, 25; *see also* Ex. 15 at 267 ("A few bruises from running around but nothing more than usual" observed at October 2017 pediatric visit). The same is true for treatment records from 2018. *See generally* Ex. 7 at 2–3, 7; Ex. 8 at 144; Ex. 19 at 214; Ex. 21 at 13. And there is no evidence that K.W. was ever diagnosed with a chronic, recurring form of ITP.

Petitioner, however, stresses record evidence of pediatric recognition of an ongoing *risk* of future bruising to K.W. (even though the evidence this occurred in association with his previously-diagnosed ITP is nonexistent). *See, e.g.*, Ex. 2 at 147, 152–54, 161 (records from October 17, 2016 pediatric visit—confirming at this time an additional MMR vaccine should not be administered); Ex. 5 at 1 (notes from December 5, 2017 visit, at which time pediatric treater took note of K.W.'s ITP history, maintaining that "[h]e continues to bruise easily" without reference to clinical observations of bruising, but otherwise noting that "[h]is platelet count is currently normal"). The records do reveal a general concern on Petitioner's part about the possibility of K.W. bruising, often maintaining to treaters that she had observed suspicious instances of susceptibility to bleeding and bruising. Br. at 17–32. But this is despite treater conclusions that ITP could not explain them. *See, e.g.*, Ex. 15 at 455, Ex. 23 at 101 (record from May 2019 visit, at which time treater proposed reference to hematology "[g]iven mother's ongoing concern and [K.W.'s] tendency to bruise (*despite normal platelets and coags several times in past 2 years*)" (emphasis added). These same records reveal Petitioner's specific concern about the possibility of vaccines exacerbating the issue. *See, e.g.*, Ex. 15 at 458–59.

[6] In another emergency care visit record from June 2018, Petitioner similarly reported to treaters that K.W.'s platelet levels had dropped below normal in December 2017. Ex. 19 at 234. But no record to corroborate this contention has been filed in the record for this petition.

II. Procedural History

As noted above, Petitioner initiated her claim in March 2019. The matter was assigned to the "Special Processing Unit," based on the view that a Table ITP case was likely to settle. However (and after several years of attempts by Petitioner to gather records relevant to the claim), Respondent represented in his Rule 4(c) Report, filed in June 2021 (ECF No. 64), that Petitioner could not meet the severity requirement under the Vaccine Act.

I subsequently ordered Petitioner to show cause whether dismissal of the claim was appropriate, in light of Respondent's objections. *See* Order, dated September 1, 2021 (ECF No. 65). But more delay ensued (in part to allow for a decision in a pending, related Federal Circuit case discussed below). Petitioner also moved for permission to obtain an expert to support her severity arguments. See Motion to Appoint Expert, dated April 3, 2022 (ECF No. 73). I later denied the motion. *See* Docket Entry, dated February 23, 2023. Eventually, the parties briefed the severity question, and the matter became ripe for decision this past August—nearly *two years* after the severity issues were not only raised but made the topic of the Show Cause Order.

III. Parties' Arguments

Petitioner

Petitioner contends that she can establish severity. She maintains that the fact that K.W. was excused from receiving additional doses of the MMR vaccine, due to a potential susceptibility to ITP based on his first experience in April and May 2016, is evidence of the "residual effect" required by the Act. Br. at 35. She argues that the opinion of an immunologic expert would substantiate the risk. *Id.* She further maintains that although controlling Federal Circuit precedent (discussed below) seems to define the issue as a question of law, it actually presents a mixed question of law and fact—with the latter requiring the expert's assistance. *Id.* at 36. Thus, although she does not contest that mere platelet monitoring or bruising *alone* are not proof of severity, "there is a factual question as to whether the proscription against further vaccination . . . reflects a medical determination" that a permanent vulnerability has been caused by the injury. *Id.* at 37.

Accordingly, Petitioner deems the fact that there is no record evidence of a reduced platelet count after three months post-vaccination to be "beside the point." Br. at 38. This amounts to only one indicia of the vaccine's causal impact. And in fact, Petitioner goes on to maintain, the evidence of future vaccine restriction or exemption (which she reiterates, at great length, from earlier in her brief) as recommended by subsequent treaters is evidence of that impact. *Id.* at 39–43. She also cites a number of items of literature emphasizing the relationship between the MMR vaccine and ITP (and specifically the risk of future incidents if again vaccinated). *Id.* at 43–48.

Petitioner also offered a reply in further support of her arguments about severity. She emphasizes again that K.W.'s treaters have recommended against future receipt of the MMR vaccine, and that this restriction existed for several years from his ITP onset. Reply at 1–2. She deems this to constitute a "residual effect," even under recent relevant Federal Circuit case law (discussed below), stressing that a disease/injury can *exist* even if obvious/clinical signs of it are not evident. *Id.* at 2–3. Because treaters deemed K.W.'s health threatened by future vaccination, his "immune system was somatically changed by his MMR-caused ITP." *Id.* at 3. And Petitioner maintains it is not the risk *itself* that is the change, but the very fact of an inability to receive the MMR vaccine later. *Id.* at 5, 7 ("the restriction itself is a residual effect").

In addition, Petitioner maintains that the severity issue does not, as Respondent argues, involve purely a question of law, but a mixed issue of law and fact (even if it is true that the Federal Circuit's reading of the severity requirement is legal in nature). Reply at 4. And she purports that "the opinion of an expert immunologist" would provide an explanation for the vaccination restriction. *Id.* at 7.

Respondent

Respondent deems Petitioner's inability to meet the severity requirement fatal to the claim. Opp. at 1–2. He characterizes Petitioner's brief as "a longer recitation of her motion for leave to retain an expert," but notes that no new actual evidence has been offered (other than what was already noted in the record to be insufficient) establishing severity. Respondent differentiates ongoing treatment, or demonstrated concerns about the ongoing impacts of, or deficits attributable to, a specific injury from the lack of evidence herein that K.W.'s platelet counts again dropped outside of six months post-onset. *Id.* at 2–3. He also argues that Petitioner's literature is unhelpful. Some items only propose a *possible* increased risk of ITP post-vaccination (based, moreover, on limited data), while other articles are specific to *chronic* ITP—a diagnosis inapplicable to K.W. *Id.* at 3–4. Respondent ultimately deems the increased risk of recurrence pointed to by Petitioner to be speculative, adding that Petitioner's arguments, if accepted, would mean that any individual who experiences vaccine-caused ITP could meet the severity requirement, "regardless of how quickly the ITP resolves," simply because of a *possibility* of recurrence. *Id.* at 4.

IV. Applicable Legal Standards

A. *Burden of Proof for Table Claims*

Petitioner pleaded her case as a Table claim (although she also asserts a non-Table claim, given that K.W. received several vaccines—but only the MMR vaccine is the subject of a Table claim for an ITP injury). Pet. at 1. Table claim petitioners need not independently demonstrate that

the vaccine at issue can cause the claimed injury, nor that the vaccine did cause the injury in that case. *Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995). Instead, as long as the claimed injury (as defined by the Table, of course) occurred within a medically reasonable time frame following vaccination, causation is presumed. *Id.*

This presumption of causation does not excuse Table claim petitioners from other statutory requirements for compensation, however. *Song v. Sec'y of Health & Human Servs.*, 31 Fed. Cl. 61, 65 (1994), *aff'd*, 41 F.3d 1520 (Fed. Cir. 1994) (unpublished decision); *Crabbe v. Sec'y of Health & Human Servs.*, No. 10-762V, 2011 WL 4436724, at *1 (Fed. Cl. Spec. Mstr. Aug. 26, 2011). Thus, Table or not, Vaccine Program claimants not asserting a vaccine-related death or other injury requiring a surgical intervention and inpatient care must demonstrate that they suffered the residual effects or complications from their vaccine-related injury for more than six months. Section 11(c)(1)(D).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d

543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

B. *Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993). Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later statements: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to

afford greater weight to contemporaneous medical records or other evidence, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, even though she asks for the opportunity to present expert testimony on the severity issue. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

As I have previously noted, "thrombocytopenia" is a condition involving decreased platelet counts, with the form relevant to a Vaccine Act claim attributable to an immune system-mediated process (as opposed to being caused by a medicinal side effect or other comorbidity) that results in platelet destruction. *Wright v. Sec'y of Health & Hum. Servs.*, No. 16-498V, 2019 WL 1061472, at *2 n.8 (Fed. Cl. Spec. Mstr. Jan. 18, 2019), *mot. for review granted, decision rev'd*, 146 Fed. Cl. 608 (2019), *rev'd, decision reinstated,* 22 F.4th 999 (Fed. Cir. 2022); *Gramza v. Sec'y of Health & Hum. Servs.*, No. 15-247V, 2018 WL 1581674, at *1 n.4 (Fed. Cl. Spec. Mstr. Feb. 5, 2018), *mot. for review den'd,* 139 Fed. Cl. 309 (2018). Thus, critical to ITP's diagnosis is blood test evidence of lowered platelet levels (even if what often indirectly "tips off" a treater to ITP's presence is clinical proof of unexplained bruising or petechiae).

One critically-important aspect of ITP is that it is attributable to some kind of underlying immune system dysfunction. D. Cines et al., *Congenital and Acquired Thrombocytopenia,* 1 Hematology Am. Soc. Hematol. Educ. Program 390 (2004), filed as Ex. 26 (ECF No. 83-1). While ITP may be *triggered* by a vaccine, however, this does not mean that a person's unique

susceptibility to ITP is vaccine-caused. ITP can occur in the absence of vaccination, can be triggered by other external stimuli—and can occur without any identifiable trigger whatsoever.[7]

Petitioner has asserted both a Table and non-Table claim based on K.W.'s ITP—but as noted above, *all* Program claim's are subject to the "severity requirement" of establishing at least six months of post-onset sequela. Thus, an inability to establish severity could be dispositive of the Petition in this case entirely, regardless of whether the other elements of the individual claims are met.[8] Here, Petitioner's severity arguments are unpersuasive given the record—and, more importantly, inconsistent with controlling Federal Circuit case law that explains why this case is not tenable.

It is the *Wright* decision (22 F.4th 999 (Fed. Cir. 2022)) that sets the standard for how to apply the test for severity in the context of ITP (although it contains useful analysis applicable to other kinds of injuries as well). *Wright* was the end-result of a case I originally decided. I initially found that blood testing performed to confirm the existence of ITP was not itself a "residual effect," and because the petitioner could not demonstrate any other injury sequelae that exceeded six months of onset, the case was appropriately dismissed. *Wright,* 22 F.4th at 1004 (recounting procedural history). On review, however, the Court of Federal Claims deemed such ongoing/monitoring testing (which occurred in reaction to concerns of bruising) to fall within the remit of a physician's standard of care in treating a patient with ITP, and would not have been performed "but for" the injury—meaning it was caused by the vaccine injury, reflected additional treatment of it, and therefore established severity. *Id.*

The case was remanded, and I decided damages in the petitioner's favor—but Respondent appealed, and the Federal Circuit reversed the Court. *Wright,* 22 F.4th at 1008. In so doing, the

[7] Indeed, "idiopathic purpura" is defined as "a type of thrombocytopenic purpura that **is not directly associated with any definable systemic disease but often follows a systemic infection**; it has been found to be an autoimmune condition, caused by antigens against platelets, resulting in ecchymoses, petechiae, and other bleeding. There are both acute and chronic forms: the acute form has a sudden onset, is more common in children, and usually resolves spontaneously within a few months; the chronic form has a slower onset, is more common in adults, and may be recurrent." *Idiopathic purpura*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=101150 (last accessed December 1, 2023).

[8] Since K.W. received an MMR vaccine, the more easily-established claim would, in theory, be a Table claim for ITP after the MMR vaccine (since there is no comparable claim for other vaccines). 42 U.S.C.A. § 300aa-14(a)(V)(A). However, manifestation of ITP in such circumstances must begin no later than 30 days after vaccination – and it is not evident Petitioner can so demonstrate. As my review of the facts above illustrates, Petitioner reported that K.W. first manifested clinical evidence that is often a harbinger of ITP two days prior to his visit to the ER on May 12, 2016, or May 10th – which if so would mean his ITP onset (for Table purposes) began *more* than 30 days after the April 8th vaccinations. Ex. 4 at 122-25. However, Petitioner correctly notes in opposing dismissal that the current focus is severity, and that the parties have not endeavored to address also the other elements of the claim(s). Br. at 33 n.10. I therefore will not resolve these issues (and need not, since I deem severity dispositive – even *assuming* a Table onset could be established).

Circuit explained carefully how the phrase "residual effects" (which appears directly in the Act)[9] should be understood. The Circuit explained that, as a general matter, the phrase should be understood to mean "something remaining or left behind from a vaccine injury—that "never goes away or that recurs after the original illness," in connection with an injury's *somatic* nature. *Id.* at 1005. This means "conditions within the patient"—not testing (otherwise not itself detrimental to a patient's health) designed to see *if* those conditions exist or not. *Id.* at 1006. The platelet count blood testing was too non-invasive to rise to that level, and was not otherwise commensurate with treatment that assisted in care for a demonstrably-ongoing condition (and that if not performed might cause the party's health to decline). *Id.* at 1007.

For purposes of an ITP injury, severity means a claimant must demonstrate six months of ITP-associated effects—lower platelet measurements, and/or evidence of sequelae associated with that (for example, bruising or petechiae, or some other physical condition attributable to a platelet deficiency). But here, evidence of low platelet counts ceases to appear in the record after July 2016—at best, a little more than *three months from onset* (assuming that occurred in mid-April 2016). There is no evidence thereafter of another such platelet count reading, despite Petitioner's concerns for bruising. In addition, Petitioner was never diagnosed with chronic ITP—a condition that might more easily be shown to satisfy the severity requirement.[10]

Petitioner can point to no other evidence that would fill this evidentiary omission. Indeed, she virtually concedes there *is* no evidence of low platelet counts consistent with ITP after six months of manifestation/onset. However, she argues that the fact that treaters *viewed* the risk of ITP recurrence significant enough to exempt K.W. from vaccination, or simply advise against it, suggests the existence of some kind of immune-caused susceptibility that could constitute the kind of somatic, residual impact that *Wright* instructs is necessary for severity to exist.

This argument, however, amounts to an effort to evade the plain language of *Wright*. *Wright* clearly deems some kind of physical, somatic impact of the vaccine injury to be the essence of an injury's "residual effect." Lingering *risk of a future injury* after a second vaccination, by contrast, is not evidence of "effects within the patient"—"lingering signs, symptoms, or sequelae characteristic of the course of the original vaccine injury." *Wright,* 22 F. 4th at 1006. It is at most a reasoned guess that the injured party's susceptibility means recurrence is possible. In *Wright,* the possibility of recurrence was addressed by blood testing; here, Petitioner points to treater recommendations against future vaccination. But in each case, the treatment decisions reflect the

[9] *See* Section 11(c)(1)(D)(i).

[10] For this reason, I do not entertain literature filed in this case specific to the distinguishable condition of *chronic* ITP. *See,* e.g., A. Bibby et al., *Is MMR Immunisation Safe in Chronic Idiopathic Thrombocytopenic Purpura?,* 93 Archives of Disease in Childhood 354 (2008) Ex. 30 (ECF No. 83-5); R. Drachtman et al., *Exacerbation of Chronic Idiopathic Thrombocytopenic Purpura Following Measles-Mumps-Rubella Immunization,* 148 Archives of Pediatric and Adolescent Medicine 326 (1994), Ex. 35 (ECF No. 83-10).

medical view that there is a *risk* of recurrence. No matter how well-informed the supposition of risk might be,[11] however, recurrence has yet to occur—and may never (and if it does, a party is not precluded from bringing a second Vaccine Act claim to obtain compensation for a subsequent, injury-causing vaccination).[12] It is therefore a *speculative* concern. Professional recommendations against vaccination *are not evidence of a residual effect*.

To some degree, Petitioner's argument conflates vaccine *causation* with *susceptibility* to a vaccine injury in the first place. Petitioner seems to suggest that treater recommendations against future vaccination are evidence of concern about some new, somatic "change" in K.W. post-vaccination that is attributable to it. In fact, susceptibility is a common theme in Program cases (and often does a lot of work on behalf of claimants). Petitioners almost always argue that the reason they experienced a rare vaccine injury that the majority of vaccinated individuals do not has something to do with an underlying, if not well-understood, propensity (genetic or otherwise) or sensitivity to the vaccination as trigger that cannot otherwise be explained—and these arguments are often deemed credible.[13] *See,* e.g., *James ex rel. Chee v. Sec'y of Health & Hum. Servs*., No. 09-284V, 2010 WL 4205699, at *17 (Fed. Cl. Spec. Mstr. Sept. 30, 2010) (finding that acellular pertussis vaccine can in rare cases cause apnea and cardiac arrest, resulting in death, in a "medically fragile" child). And claimants need not establish susceptibility with certainty, and usually rely on an expert opinion that it is likely a vaccine interacted with some underlying susceptibility, even if the latter could not be precisely identified. *Flores v. Sec'y of Health & Hum. Servs*., 115 Fed. Cl. 157, 163–64 (2014) (special master committed error in requiring petitioner to

[11] It should not be assumed that treater recommendations against future vaccination are per se scientifically or medically valid. Evidence in many Vaccine Program cases establishes that treaters often indulge patient concerns about vaccination effects in the past by providing vaccine exemptions, out of a reasonable desire to meet the patient's needs. *Morris v. Sec'y of Health & Hum. Servs.*, No. 13-601V, 2017 WL 2461226, at *15 (Fed. Cl. Spec. Mstr. May 9, 2017) (noting that petitioner's PCP agreed to provide a letter exempting her from future vaccination based in part on her prior experience, but that the actual records in the case suggested that the PCP was skeptical of a connection between the vaccine and petitioner's injury). It cannot be concluded *in every case* that such a recommendation is well-founded.

Regardless, such evidence at best goes to causation (since it can reflect a treater view that vaccination caused the injury), and thus helps satisfy the second *Althen* prong. *See,* e.g., *Robinson v. Sec'y of Health & Hum. Servs*., No. 14-952V, 2021 WL 2371721, at *24 (Fed. Cl. Spec. Mstr. Apr. 12, 2021) (giving weight to evidence that treater regularly advised injured party against vaccination as supportive of petitioner's prong two burden). But here, at least for purposes of the Table claim at issue, causation is presumed, and the vaccination restrictions are pointed to in substantiation of something entirely different.

[12] In fact, this has occurred in the past (albeit rarely) – where a claimant was able to bring a second claim based on a subsequent vaccination and alleged injury. *See, e.g., Rowe v. Sec'y of Health & Hum. Servs*., No. 20-740V, 2023 WL 5322699, at n.3 (Fed. Cl. Spec. Mstr. July 14, 2023); *Veytsel v. Sec'y of Health & Hum. Servs.*, No. 23-428V, 2023 WL 4557047 (Fed. Cl. Spec. Mstr. June 14, 2023).

[13] In some cases Respondent endeavors to show that a preexisting susceptibility is the "factor unrelated" cause of the injury (for example, a known genetic mutation). *Stone v. Sec'y of Health & Hum. Servs.,* No. 04-1041V, 2010 WL 1848220 (Fed. Cl. Spec. Mstr. Apr. 15, 2010). But more often than not, there is no way medically or scientifically to understand why one person would be injured by a vaccine when the majority of recipients are not.

establish precise nature of genetic susceptibility, instead of accepting expert opinion that susceptibility was likely), *aff'd*, 586 F. App'x 588 (Fed. Cir. 2014).

But rarely, if ever, in my experience is future susceptibility *itself* defined as the primary vaccine injury. And the evidence in this case hardly demonstrates that the MMR vaccine (to rely on the one most closely, and credibly, associated with the non-chronic form of ITP at issue herein) causes a child to be *sensitive in the future* to platelet count drops. Rather, literature supports the conclusion that platelet numbers decrease through an immune system-stimulative process. F. Oski and L. Naiman, *Effect of Live Measles Vaccine on the Platelet Count*, 275 New England Journal of Medicine 352, 355 (1966), filed as Ex. 34 (ECF No. 83-9). But this process does not continue on. U. Nieminen et al., *Acute Thrombocytopenia Purpura Following Measles, Mumps, and Rubella Vaccination. A Report on 23 Patients*, 82 Acta Paediatrica 267 (1993), filed as Ex. 31 (ECF No. 83-6) ("The pathogenic mechanisms of acute ITP have been suggested to differ from those involved in chronic ITP' the latter is supposed to be of autoimmune origin."). While an individual's unique genetic makeup may explain why such an autoimmune process would occur in the first place, that is not the same as the determination that vaccination is the *cause* of susceptibility.

None of the above would be resolved by permitting expert input on this issue (and thus my denial of the motion to allow an expert opinion was proper—and in keeping with the usual discretion special masters enjoy in deciding what kinds of discovery are necessary to resolve a case). As the Federal Circuit noted in *Wright*, the question of what "residual effects" establish severity presents a *legal* issue. *Wright,* 22 F.4th at 1004. Although Petitioner is correct that the proper weighing or reading of medical record proof might in many cases fairly require expert input, here the record is clear: K.W. did not experience elevated platelet counts for more than six months post-vaccination. Thus, any expert opinion would merely be employed to further vouch for Petitioner's "residual effect" arguments, and hence amount to a legal opinion. K.W. has not been shown to have again experienced a platelet drop or any of the clinical manifestations of it, and expert testimony cannot undermine that central fact.

The difficulty Petitioner faces in marshaling proof of severity in this case is somewhat due to the nature of ITP as an autoimmune disorder. Unlike many vaccine injuries litigated in the Program, ITP is readily *treated and ameliorated* once identified. As a result, the fact that it can be *caused* by a vaccine (something that Table acknowledges for at least the MMR vaccine) does not mean an individual *should* receive damages without regard to the Act's severity requirement if the injury resolves in less than six months. *This is the precise intent of the severity requirement*—to exclude what might end up being a minor injury from compensation, in favor of more significant injuries. *Wright,* 22 F.4th at 1006–1007 (discussion of Congressional intent in severity requirement).

It is for this reason that one case highlighted by Petitioner—*H.S. v. Sec'y of Health & Hum. Servs*., No. 14-1057V, 2015 WL 1588366, at *3 (Fed. Cl. Spec. Mstr. Mar. 13, 2015)—is ultimately inapposite. Reply at 3, 4-5. *H.S.* involved a Table syncope injury, in which the vaccine-induced syncopal incident (based on a vaccination received in mid-summer) *then* resulted in a fall, causing the claimant to hit the back of his head and then fracture his skull. *H.S.,* 2015 WL 1588366, at 1. The injured individual was instructed within a month of the fracture's occurrence to avoid school sports (since he was now wearing a neck brace)—and that instruction was later extended through the spring of the following year (and thus exceeded the six-month timeframe, measured from the date of vaccination). *Id.* at 2. The injured party had in the meantime been permitted to cease use of the neck brace, but otherwise his treaters believed he "had not returned to his pre-vaccination condition of health." *Id.* at 3.

One thing stands out in distinguishing *H.S.* from K.W. herein. An injury sustained *after but in connection with* syncope caused by a vaccine is not the same as ITP directly caused by vaccination. The syncope was not treated thereafter in *H.S.,* for it was inherently self-limiting and transient). But the physical fracture was, and this is what posed an ongoing issue that did not require mere monitoring. Thus, a somatic effect of the vaccination in *H.S.* was what exceeded the six month timeframe—whereas here there is no further evidence of ITP. It is conceivable that a vaccine-caused case of ITP could *also* result in bodily effects lasting longer than six months of onset,[14] but that did not occur under the facts of this case.

At bottom, Respondent correctly highlights the sweeping implications of Petitioner's argument. As noted, vaccine injuries are rare in part because most individuals do not possess the "x factor" susceptibility that K.W. likely possesses. But if mere susceptibility, exposed after a vaccination, is defined as a residual effect of vaccination, the severity requirement would be rendered meaningless—as *all Program claimants could equally maintain* that their susceptibility, now unmasked by a single vaccination, amounts to an unending risk of future harm that is itself compensable, even if the primary harm was ameliorated quickly.

CONCLUSION

Having reviewed the medical records, expert reports, medical literature, and the parties' respective arguments, I do not find that Petitioner has shown with sufficient preponderant evidence

[14] For example, if bruising or petechiae caused by ITP later resulted in some kind of complication, or required additional treatment outside of treating the ITP-related platelet drops. Or if the ITP was not brought under control within six months of manifestation.

that B.W.'s ITP or its residual effects lasted for more than six months. Accordingly, Petitioner has not established entitlement to an award of damages and I must **DISMISS** her claim.[15]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[15] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.